

REMARKS/ARGUMENTS

Applicant responds herein to the Office Action dated November 29, 2007.

Claims 1-31 and 33-35 are pending in the instant application and stand rejected.

In the Office Action, the Examiner rejected the claims as follows. Claims 1-12, and 33-35 were rejected under 35 U.S.C. §103(a) as being unpatentable over Oberlander (6,554,852) in view of Fenton Jr. (6,056,751). Claims 1-19 were rejected under 35 U.S.C. §103(a) as being unpatentable over Oberlander (6,554,852) in view of Fenton Jr. (6,056,751) in view of Sasaki *et al.* (5,735,183). Claims 1-20 as well as claim 21 were rejected under 35 U.S.C. §103(a) as being unpatentable over Oberlander (6,554,852) in view of Fenton Jr. (6,056,751) in view of Sasaki *et al.* (5,735,183) in view of Runck *et al.* (3,832,139). Claims 1-12 and 22-30 were rejected under 35 U.S.C. §103(a) as being unpatentable over Oberlander (6,554,852) in view of Fenton Jr. (6,056,751) in view of Bone (3,875,648). Claims 31 was rejected under 35 U.S.C. §103(a) as being unpatentable over Oberlander (6,554,852) in view of Fenton Jr. (6,056,751) in view of Bone (3,875,648). The objections are respectfully traversed for the following reasons.

The Examiner avers on page 8 of the Office Action that Oberlander teaches the claimed invention except for the rigid fixing means having two legs, at least one leg being adapted for insertion in one of said axial passages [sic]. Applicant assumes that the Examiner intends to say that “Oberlander teaches the claimed invention having two legs, at least one leg being adapted for insertion in one of said axial passages except for the rigid fixing means.” But he then contends that this feature, namely the *rigid fixing means* is taught by Fig. 10 in Fenton Jr.

At the outset, Applicant respectfully disagrees with the Examiner’s statement on page 2 of the Office Action that Oberlander discloses a sternum closure system. Nothing in this reference supports the assertion, and it appears to be erroneous. Thus, Oberlander relates to devices and methods for re-attaching soft tissue to bone as clearly stated at col. 2, lines 54-55. Fenton Jr. relates to the same technique. Neither is even remotely concerned with a sternum closure system, which is used during surgery in the thoracic cavity where to gain access to the thoracic cavity it is necessary to cut through the sternum. After the completion of surgery, the two halves of the sternum must now be re-approximated – i.e. brought near each other and maintained in position

while the bone fuses. Contrary to the Examiner's repeated statements, there is nothing in Oberlander or Fenton Jr. that relates to this technique.

Furthermore, the Examiner acknowledges that Oberlander fixing means is not rigid but appears to maintain his previous assertion that Oberlander's fixing means is *releasably* connected to the first and second anchor means. This is respectfully disputed and if the Examiner maintains otherwise, then the Examiner is requested to show where Oberlander teaches that his *flexible* fixing means is *releasably* connected to the first and second anchor means, notwithstanding applicant's detailed reasoning in the previous response to the contrary.

But even apart from this, applicant reiterates that both Oberlander and Fenton Jr. relate to re-attachment of soft tissue to bone (generally termed "*tissue growth*") and not to re-approximation of the two halves of the sternum. This being the case, there cannot possibly be any motivation to combine the two references as suggested by the Examiner to produce a sternal closure system as required by MPEP 2143.01 § VI, which states:

Obviousness can be established by combining or modifying the teachings of the prior art to produce the claimed invention **where there is some teaching, suggestion, or motivation to do so.**

Applicant agrees that Fenton Jr. teaches with reference to Fig. 10 a pair of interconnected bone anchors that are adapted to be disposed inside a bone. It is not clear whether the interconnection realized by a bondable band 60 shown in Fig. 10 is flexible or rigid. But it is respectfully pointed out that (i) the band 60 is used as a tissue capture region 9; and (ii) it is **fused** to the bone anchors. [Col. 6, lines 23-25].

Thus, even supposing for the sake of argument that Fenton Jr.'s fixing means is rigid, the feature that the fixing means that is *releasably* connected to the first and second anchor means is absent in Fenton Jr. The Examiner observes that Fenton Jr. at col. 6, lines 33-38 discloses the application of energy to the fixing means but surprisingly omits that the same paragraph teaches that the energy causes *localized melting of the components so as to fuse them together at the location of their mutual engagement*. It is clear that once this is done, the rigid fixing means cannot be *releasably* connected in the sense that it can be removed and re-assembled as can be

done with the rigid fixing means employed by the present invention as described, for example, in para. 108 of US 2006/0161161 where it is stated:

[0108] When it is necessary to perform a post-operative surgical procedure within the thoracic cavity, **the rigid connection of screws 10 and 12 with staple 14 may be disassembled via apparatus 150 for removing the fixing means.** To this effect staple 14 is hooked by spring-loaded grasping member 158 of apparatus 150 movably disposed within body 152, and the pressure lever 160 pivotally mounted within the upper part of hollow body 152 is turned. This pressure lever 160 operatively connected with spring-loaded grasping member 158 moves the latter relative to the stops of apparatus 150 and hence withdraw staple 14 from screws 10 and 12. This procedure is repeated as many times as many staples have to be withdrawn. Then there is performed a post-operative surgical procedure within the thoracic cavity. **Further, if necessary, the procedure of assembling a rigid connection of screws 10 and 12 with staples 14 may be repeated again.**
[Emphasis added]

In other words, the invention allows assembly and disassembly of the staple 14. This is clearly not the case with Oberlander or with Fenton Jr.

Based on the previous arguments raised by the Examiner, it appears that he has construed the limitation “releasably” to apply even when the release of the fixing means constituted by the suture in Oberlander or by the fused band in Fenton Jr. would cause irreparable damage to the fixing means. Thus, he asserted at page 19 of the previous Office Action, that Oberlander teaches “the fixing means are adapted to *releasably* connect the first and second anchor means since the fixing means are capable of being detached from the fixing means, for example by *wire cutters or a saw*” (emphasis added). The same would apply to the *fused* band in Fenton Jr.

Unfortunately, in the present Action the Examiner does not relate to this distinction in claim 1 and applicant is therefore left unsure whether the Examiner has simply overlooked it or is not persuaded by applicant’s previous arguments.

In any case, in order to read away from such a construction of the term *releasably*, applicant has replaced this term with the more detailed limitation that:

the legs of said rigid fixing means being adapted for subsequent extraction from the respective axial passages and for re-insertion therein.

No new matter is thereby added since this feature is fully disclosed in para. 108 as explained above.

With respect to the rejection of claim 1 as being obvious over Oberlander, in view of Fenton Jr. and Sasaki *et al.*, Sasaki *et al.* teaches a power screwdriver. Nowhere in Sasaki *et al.* is there any reference to a sternal closure system of the kind described in the present application or by Oberlander and Fenton Jr. At best, the device disclosed by Sasaki *et al.* might have some relevance for insertion of the anchor means – but it certainly does not teach the limitations of claim 1. Similar arguments apply also to Runck *et al.* Bone discloses a fastener for attaching buttons and the like to fabric [col. 2, lines 5-7]. The Examiner asserts on page 13 of the present Action that:

Bone discloses a fixing apparatus for placing and removing said fixing means adapted for rigidly securing to one another said first, at least one anchor means, adapted to be disposed with the left half of the sternum ...

The Examiner has merely read the language of claim 1 on to Bone without any attempt to show how Bone's fastener could be employed in a sternal closure system of the kind described and claimed in the present application. At best there is a superficial pictorial resemblance between Fig. 19, which shows a flexible filament 61C attached at opposite ends thereof to respective end bars 61A and 61B. The filament is flexible not rigid [see col. 4, line 13 and as dictated by the application to which it is put]; the filament certainly is not releasable from the end bars without completely invalidating or neutralizing its effectiveness as an attachment; and the end bars do not meet the limitations of the anchors as defined by claim 1 of the present application.

Having said all this, it is respectfully submitted that not only do neither Oberlander nor Fenton Jr. teach the limitations of the claims, but there is in fact **no motivation** in either of these references to replace their permanently attached joiner elements with the releasable fixing means as recited in the claims. Both Oberlander and Fenton Jr. are directed to devices and methods for re-attaching soft tissue to bone [see Oberlander col. 2, line 55; and Fenton Jr., Abstract]. Both devices operate on the principle of fixing one or more anchors in the bone and **permanently** connecting a flexible growth medium such as the suture 30 taught by Oberlander or the band 60 as taught by Fenton Jr. Thus, as noted in Fenton Jr., col. 4, line 2 the anchor element 12 and the joiner element 26 are permanently attached; and col. 6, line 50 the band is fused to the bone

anchor element 12 to define a tissue capture region 36. The purpose of this is well explained by Fenton Jr. at col. 1, lines 10-18 where it is stated:

In the surgical repair of soft tissue, such as, for example, the surgical reattachment of a torn ligament to bone, it is known to use multi-part devices to fix the soft tissue to the bone. The multi-part devices typically include a screw or other bone anchoring device, and a button-like device for anchoring the suture therein. The anchor is installed in a predrilled hole in the bone, and the soft tissue is fixed to the anchor in the bone with sutures, which are fastened together with the button instead of with knots.

In other words, the sutures and replacement joiner element taught by Oberlander and Fenton Jr. are not intended to maintain two halves of the sternum in proper spaced relationship but rather are intended to anchor soft tissue such as a torn ligament to bone. And while it is true that Fenton Jr. shows in Fig. 10 a band anchored between a pair of posts 12, here also the band is used as a tissue capture region that allows tissue 38 to grow in the space between the two posts. The two posts are not used to re-approximate opposite halves of the sternum during a surgical procedure i.e. to maintain them in proper spaced relationship.

Consequently, there is no basis to suggest that the devices taught by Oberlander or Fenton Jr. are equally well adapted to maintain two halves of the sternum in proper spaced relationship where the rigidity of the fixing means constituted by the staple 14 is essential.

In summary, neither Oberlander or Fenton is directed to the problem to which the invention as claimed is directed. Likewise, none of the subsidiary citations teaches or suggests a sternal closure system having a pair of anchors having axial passages for accommodating therein respective ends of a rigid fastener that is adapted to for repeated insertion and extraction.

New claim 36 recites the same features in somewhat simpler language and is believed therefore to be equally allowable.

Reconsideration is accordingly requested.

Independent claims 1 and 36 are believed to be in condition for allowance. Dependent claims 2-31 and 33-35 are likewise believed to be allowable by virtue of their dependence on an amended independent claim and their presentations of additional features and elements.

Accordingly, reconsideration and withdrawal of the rejections of dependent claims 2-31 and 33-35 are respectfully requested.

The application is now believed to be in condition for allowance.

Accordingly, the Examiner is respectfully requested to reconsider the application, allow the claims as amended, and pass this case to issue.

Respectfully submitted,

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THROUGH THE UNITED STATES
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EFS FILING SYSTEM
ON FEBRUARY 26, 2008



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